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(54) Ultrasound apparatus and method for securing or removing a prosthesis

(57) A method of securing a prosthesis to a bone includes inserting cement into a cavity formed in the bone, locating the prosthesis in the cemented cavity and, before the cement sets, applying ultrasound to the cement through the prothesis at a frequency and for a time to substantially eliminate folds and inclusions in the cement. The ultrasonic frequency may be c. 20KHz. Alternatively, a cemented prothesis may be removed by applying ultrasound thereto firstly at a frequency to cause fatigue fracture of the cement-bone and cement-prosthesis bonds, then at a frequency to cause cavitation in the interface and finally at a frequency to cause thermal softening of the cement. The ultrasound apparatus used may include a magnetostriction transducer 20 connected to a conductive body 10 which has adjustable jaws 12 for gripping the prosthesis 4, and means for controlling the resonant frequency of the transducer.

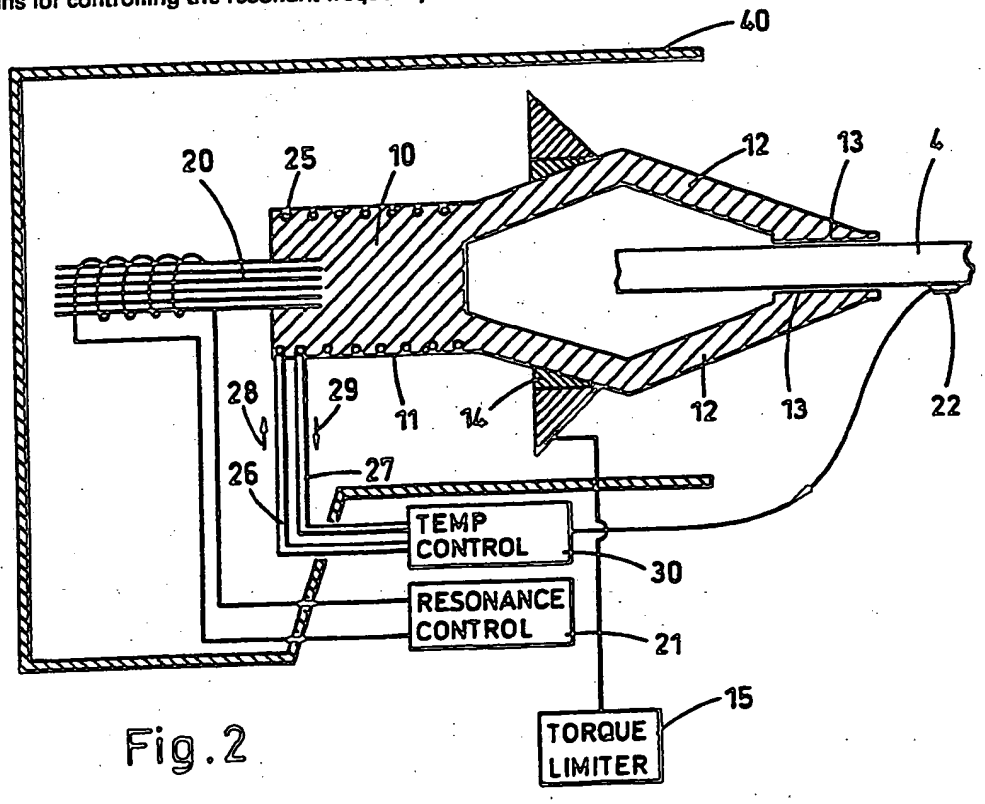

Fig.2

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

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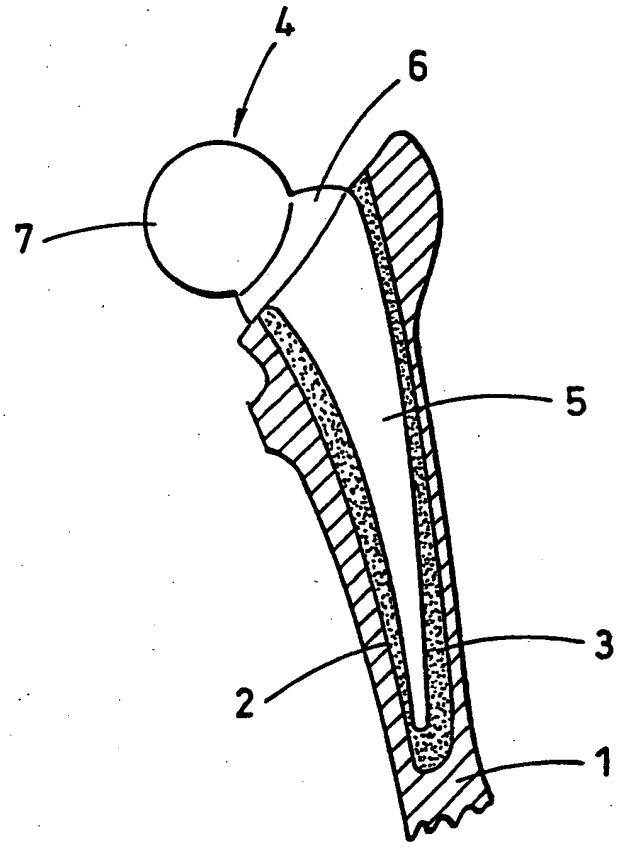

Fig. 1

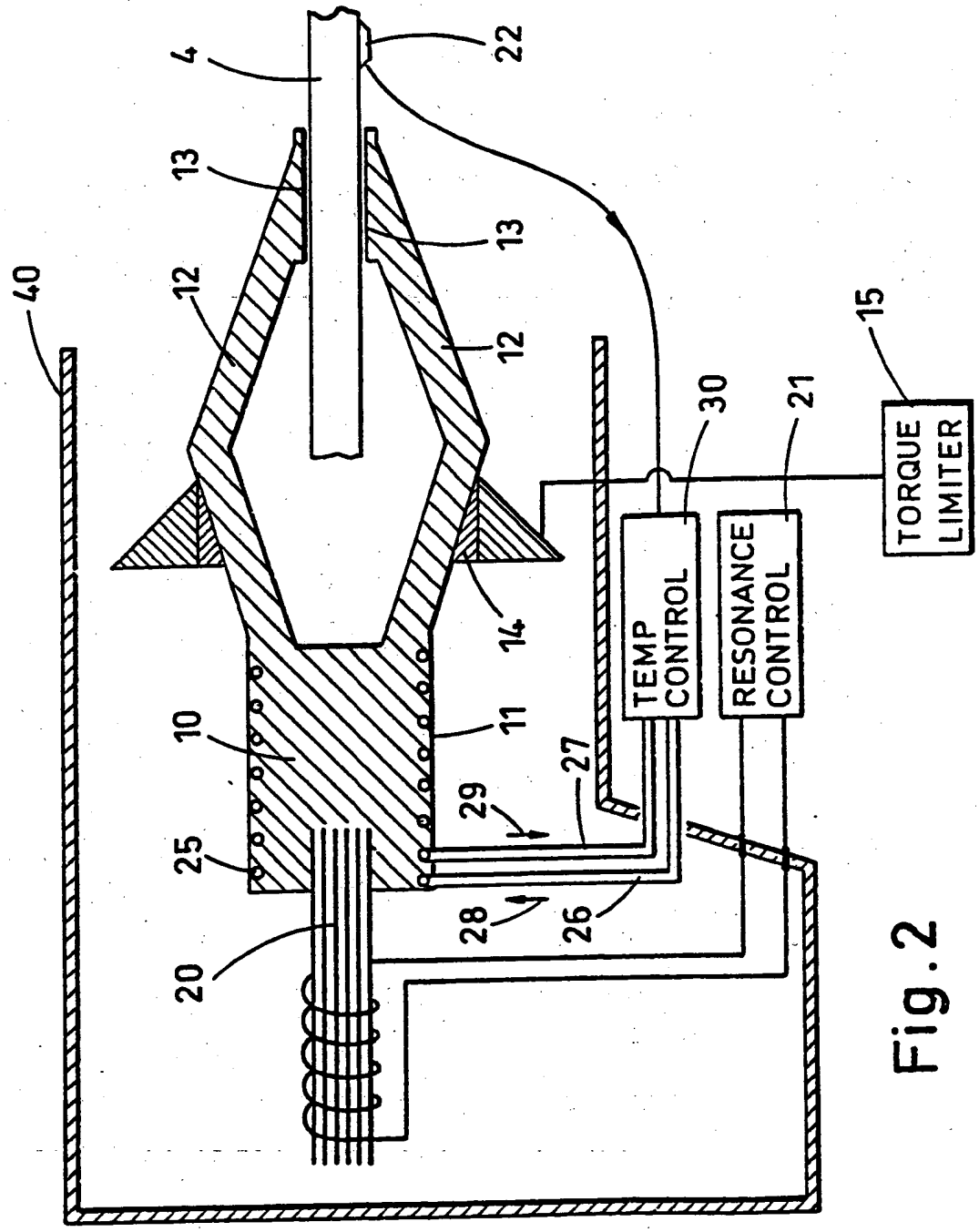
4
22
13
13
12
12
40
15
30
21
TORQUE LIMITER
TEMP CONTROL
RESONANCE CONTROL
14
10
11
27
29
25
28
26
20

Fig.2

APPARATUS AND METHOD FOR SECURING AND REMOVING A PROSTHESIS

This invention relates to a method for securing a prosthesis to a bone, a method of removing a prosthesis from a bone and an apparatus used in the aforesaid methods.

This invention, although believed to have general applicability to the fitment and removal of prosthesis is particularly useful in connection with artificial hip joints where a prosthesis is anchored to the shaft of a femur.

The anchorage of a femoral head of a prosthesis to the shaft of a femur is described in "The Journal of Bone and Joint Surgery", Volume 42B, No. 1, February 1960 at pages 28 - 30. This paper discloses exposing a hip joint, removing the femoral head and curetting the cavity of the femoral neck with a strong spoon reaching into the upper end of the medullary canal for about six inches. A cold-curing cement of, for example, low viscosity polymethylmethacrylate (PMMA) cement, such as that sold under the trade name of "Palacos LV" by Schering Corporation, is made by mixing powder (polymer) and liquid (monomer) to initiate polymerisation of the monomer, forming a dough-like mass which, after a short time, hardens into a mechanically uniform solid. When mixing the dough-like mixture, after three or four minutes when it is possible to pull "hairs" of plastic from the surface of the dough, the dough is moulded into a sausage-like shape and, after sucking the femur clear of blood, the dough-like material is pushed deep into the cavity and rammed into position. The prosthesis stem is inserted into the cement forcing excess cement out between the cut surface of the neck of the femur and the base of the femoral neck. As the narrow end of the prosthesis is followed by the progressively increasing diameter of the stem, the cement dough-like material is expanded and forced into every crevice of the interior of the femur until a cast of the

rough interior of the femur is produced. The process of setting takes about fifteen minutes from the time that mixing starts to final hardening.

It has, unfortunately, been found that mixing the cement to a dough-like consistency leaves cavities and inclusions in the cement. Although PMMA has been shown to have good load-carrying capabilities in compression, it is weak in tension, sheer, and fatigue resistance resulting in fracture of the cement and causing loosening of the prosthesis. As described by Wixson, Lautenshlager, and Novak in The Journal of Arthroplasty, Volume 2, No. 2, June 1987, at pages 141 - 149, there have been numerous attempts to strengthen the cement by adding various fillers, such as glass or carbon fibres. These methods tend to clog the opening of the pores into the trabecula bone and may result in an abnormal distribution of the fibres and local alteration in the material properties of the cement-bone interface. In this paper it is stated that none of the reinforced cements has been released by the Food and Drug Administration for general use and they are not used clinically.

So as to overcome the problem of cement-bone breakdown, Wixson et al teach that in conventional mixing of the cement, the mixing process traps small bubbles of air and as stirring of the dough-like mixture commences, the cement forms into two discrete masses or lumps which coalesce, trapping more air bubbles of a larger diameter in the mixture. To overcome this problem, Wixson et al discloses cooling the components to be mixed in an ice water bath and mixing the components in a vacuum in the range 500 - 550mmHg.

Despite the attempts at improving the fixation of a prosthesis to a bone, it is often necessary to conduct a revision process whereby an existing prosthesis has to be removed and a new prosthesis fitted. It is difficult to remove a prosthesis, and in particular the cement cast; the

existing process normally involves attempting to dislodge the prosthesis with incessant hammer blows using, for example, a so-called "slap-hammer"; removing the cement cast is even more difficult, and together they constitute the most hazardous and time-consuming part of revision surgery.

An experimental technique for loosening a prosthesis cemented in a bone is disclosed in Clinical Orthopaedics and Related Research, No. 235, October 1988, pages 261 - 267, "The effect of the extracorporeal shock wave lithotriptor on the bone-cement interface in dogs". In this reference a bone, prosthesis and cement combination are located in a water-filled bath and acoustic shock waves are caused to propagate through the water. The bone/prosthesis joint is positioned at the focal point of the shock waves, the focal point being confirmed by fluoroscopy or a pair of lasers placed perpendicularly to one another. In the experiment the shock wave is generated under water and the shock wave causes disruption of the bone-cement interface thereby loosening the prosthesis without weakening the surrounding bone.

It will, however, be appreciated that the use of such shock waves in water must be directed at the focus point, otherwise energy is dissipated and such apparatus, while suitable for treating renal and biliary stone disease, is cumbersome and impractical for use in the context of a revision hip arthroplasty.

The present invention seeks to overcome the foregoing defects and difficulties.

According to a first aspect of this invention there is provided a method for securing a prosthesis to a bone including the steps of

forming a cavity in a bone,

inserting cement into said cavity,

locating a prosthesis in the cemented cavity and before the cement sets,

applying ultrasound to the cement through the prosthesis at a frequency and for a time to substantially eliminate folds and inclusions in the cement.

Preferably, the cement is a cold-curing cement such as polymethylmethacrylate (PMMA).

Preferably, the ultrasonic frequency is approximately 20KHz.

According to a second aspect of this invention there is provided a method of removing a prosthesis cemented into a bone including the steps of

(a) applying an ultrasonic frequency to the prosthesis at such a frequency to cause fatigue fracture of bonding between the bone and cement, and between prosthesis and cement,

(b) applying an ultrasonic frequency to the prosthesis to cause cavitation by negative (tensile) pressure wave front advancing through water found in the interface between the prosthesis, cement, and bone,

(c) applying an ultrasonic frequency to the prosthesis to cause thermal softening of the cement, and

(d) removing the prosthesis.

Preferably, the frequency used for steps (a) and (c) is approximately 500KHz and the frequency for step (b) is approximately 20KHz.

Preferably, after breaking the bond between the prosthesis and cement, the prosthesis is cooled to a temperature to shrink the prosthesis with respect to the bone without damaging living tissue to assist removal of the prosthesis.

According to a third aspect of this invention there is provided an ultrasound apparatus including an ultrasonic transducer connected to a conductive body having attachment means for attaching said body to a prosthesis, and controlling means for controlling the resonant frequency of said transducer.

The attachment means comprise a pair of adjustable

jaws for gripping the prosthesis or four equi-circumferentially spaced adjustable jaws for gripping the prosthesis.

Advantageously, an adjustable clamp is provided for enabling the prosthesis to be securely gripped by the jaws.

Conveniently, said clamp is a pneumatic clamp connected to a source of compressed air and, advantageously, a torque limiting device is provided to limit the grip provided by said jaws.

Preferably, resonance sensor means is provided for detecting the resonant frequency of the ultrasonic transducer, said resonance sensor means being connected to said controlling means, whereby in dependence upon the output of said resonance sensor means, said controlling means adjusts the resonant frequency for maximum efficiency.

In a preferred embodiment, said conductive body is provided with cooling means whereby said prosthesis may be shrunk to assist removal in revision surgery.

Advantageously, said cooling means is integrally formed with said body and conveniently is supplied from a source of liquid air.

Preferably, the sensor means includes a heat detector for detecting the temperature of the prosthesis, which said heat detector is connected to apply signals indicative thereof to said control means, whereby the temperature of said prosthesis is regulated to a desired temperature, i.e. one which does not damage the bone or soft tissue.

The invention will now be described, by way of example, with reference to the accompanying drawings, in which

Figure 1 shows a cross-section through a femur and in which a prosthesis is located, and

Figure 2 shows an apparatus in accordance with the third aspect of this invention.

In the Figures like reference numerals denote like

parts.

Referring to Figure 1, a femur shaft 1 is hollowed out in any known manner, for example as discussed above in the reference, The Journal of Bone and Joint Surgery, to form a cavity 2 which is filled with polymethylmethacrylate (PMMA) cement 3. A hip joint metallic prosthesis 4 known per se having a stem 5, femoral head 6 and ball 7 is mounted in the cemented cavity 2.

The apparatus of the invention is shown in Figure 2 and has an ultrasonically conductive body 10 formed, for example, of titanium. The body has a cylindrical end portion 11 formed, for example integrally, with two or more jaws 12. In the preferred embodiment the body has four equi-circumferentially spaced adjustable jaws 12, the greater the number of jaws, the better being the propagation of ultrasonic frequency from the body 10 to a prosthesis 4. In this respect, the jaws 12 have faces 13 for securement about the prosthesis 4. A pneumatic clamp 14 is provided to securely attach the jaws about the prosthesis 4. The pneumatic jaws 14 may be connected to a torque limiting device 15 to ensure that the jaws do not clamp too tightly on the prosthesis.

An ultrasonic transducer 20, for example a magnetostriction device, is connected to the end 11 of the body 10 and the ultrasonic transducer 20 is connected to a resonance frequency controller 21. The resonance frequency controller 21 is connected with a resonance sensor (not shown) that is integrated within the ultrasound source 20 for adjusting the resonant frequency for maximum efficiency.

The end 11 of the body 10 is integrally formed with a coil 25 for transferring cooling liquid air to the body 10. The coil 25 is connected to an inlet pipe 26 and an outlet pipe 27, the direction of flows of air being as indicated by arrow headed lines 28 and 29. The inlet and outlet pipes 27 are connected to a temperature controller 30, the

temperature controller being connected to a temperature sensor in a sensor device 22 attached to the prosthesis.

The body 10 and ultrasonic transducer 20 are housed in an open ended cover 40 made, for example, of carbon fibre and intended to act as an acoustic and thermal insulator.

In a first manner of operation, when securing a prosthesis to a bone filled with PMMA cement, the jaws 12 are clamped about the prosthesis 4 using the clamp 14 and an ultrasonic frequency produced by the transducer 20 is applied to the prosthesis 4 via the body 10. The frequency of application is about 20KHz which is, in any event, at a frequency to cause cavitation thereby eliminating gaseous porosity within the still fluid cement. The application of ultrasound to the prosthesis improves the mechanical properties of the PMMA cement. In this respect, once the prosthesis is located in the cement filled bone and before the cement sets, the ultrasonic sound produces agitation to eliminate folds and inclusions within the PMMA cement and improves the grain qualities of the cement as it sets.

In another manner of operation of the invention, in revision surgery, where it is required to break the bond between the prosthesis and cement and between the cement and bone so as to be able to remove the prosthesis and the cement, again the jaws are clamped to the prosthesis 4 and ultrasound created by the transducer 20 is applied to the prosthesis 4. The frequency is initially set at approximately 500KHz to cause fatigue fracturing between the bone and cement and between the prosthesis and the cement. The frequency of the transducer is then adjusted to approximately 20KHz to create cavitation by negative (tensile) pressure wave fronts advancing through water found in the interface between the prosthesis/cement and cement/bone junctions whereby as cavitation bubbles collapse, the energy released disrupts interface bonding. Continued application of ultrasound at a frequency of about 500KHz causes thermal softening of the visco-elastic cement.

It is possible that the prosthesis can then be withdrawn from the bone, but the present invention preferably provides thermal shrinkage of the prosthesis to more readily facilitate removal of the prosthesis from the bone. In this respect, cooled air is supplied through the coil 25 to the body 10 and thence through conduction to the jaws 12 and to the prosthesis. The amount of cooling is down to a level such that the metal prosthesis shrinks but is not so low that the bone or other living tissue is damaged. The temperature of the prosthesis 4 is detected by the heat detector located within the sensor device 22 which supplies signals to the temperature controller 30.

By the use of the apparatus of this invention, the interface bonding between prosthesis/cement and cement/bone is disrupted by the combination of fatigue fracturing, cavitation effects and thermal softening of the visco-elastic cement material (PMMA). Fracturing these bonds facilitates removal of the prosthesis and of the cement. Removal of the prosthesis in revision surgery is further enhanced by shrinking the prosthesis through cooling.

CLAIMS:

1. A method for securing a prosthesis to a bone including the steps of

forming a cavity in a bone,

inserting cement into said cavity,

locating a prosthesis in the cemented cavity and before the cement sets,

applying ultrasound to the cement through the prosthesis at a frequency and for a time to substantially eliminate folds and inclusions in the cement.

2. A method as claimed in claim 1 wherein the cement is a cold-curing cement such as polymethylmethacrylate (PMMA).

3. A method as claimed in claim 1 or 2 wherein the ultrasonic frequency is approximately 20KHz.

4. A method of removing a prosthesis cemented into a bone including the steps of

(a) applying an ultrasonic frequency to the prosthesis at such a frequency to cause fatigue fracture of bonding between the bone and cement, and between prosthesis and cement,

(b) applying an ultrasonic frequency to the prosthesis to cause cavitation by negative (tensile) pressure wave front advancing through water found in the interface between the prosthesis, cement, and bone,

(c) applying an ultrasonic frequency to the prosthesis to cause thermal softening of the cement, and

(d) removing the prosthesis.

5. A method as claimed in claim 4 wherein the frequency used for steps (a) and (c) is approximately 500KHz and the frequency for step (b) is approximately 20KHz.

6. A method as claimed in claim 4 or 5 wherein after breaking the bond between the prosthesis and cement, the prosthesis is cooled to a temperature to shrink the prosthesis with respect to the bone without damaging living tissue to assist removal of the prosthesis.

7. An ultrasound apparatus including an ultrasonic

transducer connected to a conductive body having attachment means for attaching said body to a prosthesis, and controlling means for controlling the resonant frequency of said transducer.

8. An ultrasound apparatus as claimed in claim 7 wherein the attachment means comprise a pair of adjustable jaws for gripping the prosthesis or four equi-circumferentially spaced adjustable jaws for gripping the prosthesis.

9. An ultrasound apparatus as claimed in claim 8 wherein an adjustable clamp is provided for enabling the prosthesis to be securely gripped by the jaws.

10. An ultrasound apparatus as claimed in claim 9 wherein said clamp is a pneumatic clamp connected to a source of compressed air.

11. An ultrasound apparatus as claimed in claim 10 wherein a torque limiting device is provided to limit the grip provided by said jaws.

12. An ultrasound apparatus as claimed in any of claims 7 to 11 wherein resonance sensor means is provided for detecting the resonant frequency of the ultrasonic transducer, said resonance sensor means being connected to said controlling means, whereby in dependence upon the output of said resonance sensor means, said controlling means adjusts the resonant frequency for maximum efficiency.

13. An ultrasound apparatus as claimed in any of claims 7 to 12 wherein said conductive body is provided with cooling means whereby said prosthesis may be shrunk to assist removal in revision surgery.

14. An ultrasound apparatus as claimed in claim 13 wherein said cooling means is integrally formed with said body and conveniently is supplied from a source of cooled or liquid air.

15. An ultrasound apparatus as claimed in claim 12 wherein the sensor means includes a heat detector for detecting the temperature of the prosthesis, which said heat detector is

connected to apply signals indicative thereof to said control means, whereby the temperature of said prosthesis is regulated to a desired temperature.

16. A method as claimed in claim 1 and substantially as herein described with reference to and as shown in the accompanying drawings.

17. A method as claimed in claim 4 and substantially as herein described with reference to and as shown in the accompanying drawings.

18. An ultrasound apparatus substantially as herein described with reference to and as shown in Figure 2 of the accompanying drawings.

Patents Act 1977
Examiner's report to the Comptroller under Section 17 (The Search report)

Application number
GB 9308009.1

Relevant Technical Fields

(i) UK Cl (Ed.M) A5R (RAP, RAT)

(ii) Int Cl (Ed.5) A61B 19/00, A61F 2/46

Databases (see below)
(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii) ONLINE DATABASES: WPI, MEDLINE

Search Examiner
L V THOMAS

Date of completion of Search
21 JULY 1994

Documents considered relevant following a search in respect of Claims :-
1-6, 16, 17

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
X	WO 92/22259 A1	(ADVANCED OSSEOUX TECH) see line 16 page 14-line 13, page 15 and lines 7-21 page 32	4
X	WO 91/11965 A1	(ADVANCED OSSEOUX TECH) see line 35 page 4-line 12 page 5 and lines 4-21 page 8	4
X	WO 90/04953 A1	(NILSSON) see lines 10-35 page 3	1,2
X	US 5019083	(KLAPPER ET AL) see lines 10-63 column 4 and line 54 column 5 line 3 column 6	4
X	US 4248232	(ENGDBRECHT ET AL) see lines 10-45 column 4	4

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